REMARKS

By way of summary, Claims 1, 3-16, and 27-30 were pending in this application. Of these, Claims 3 and 13-16 previously were withdrawn. Claim 52 is added herein. Accordingly, Claims 1, 4-12, 27-30, and 52 remain pending for reconsideration.

Anticipation Rejection Based on Ash

Claims 1, 4-12, and 27-30 are rejected in the Office Action under 35 U.S.C. § 102(b) as anticipated by Ash (U.S. Patent No. 5,947,953 to Ash et al.).

Ash

Ash is directed to a splittable multiple catheter assembly 10 and related methods. The multiple catheter assembly 10 has a first catheter 26, a second catheter 30, and a splittable membrane 46 (See Figure 4A below).

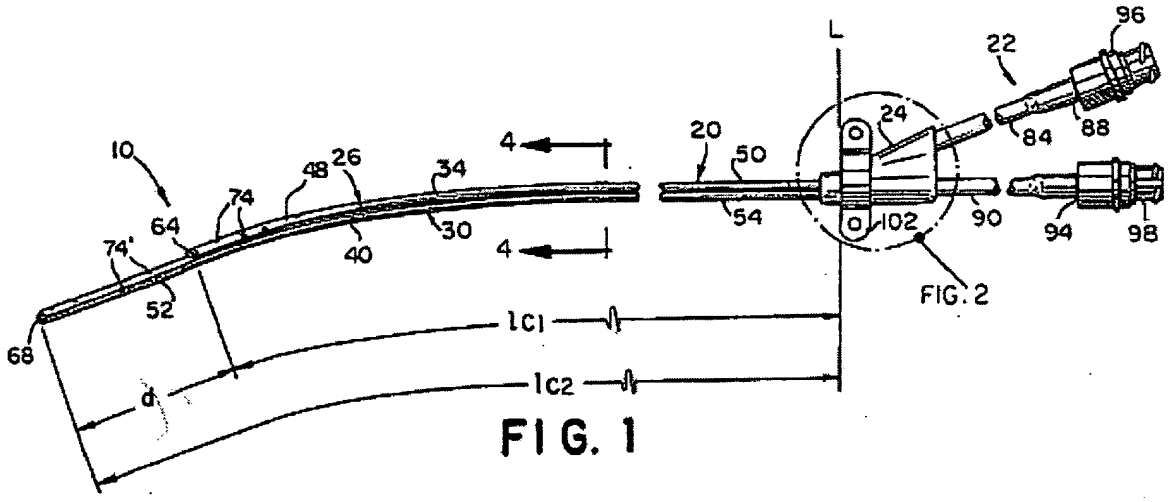

FIG. 2

FIG. 1

The first catheter 26 has a proximal tip, a distal end region terminating in a distal tip 68, and an outer surface 40 defining a first lumen 32 (See Figure 4A) extending longitudinally therethrough between distal and proximal openings. The second catheter 30 has a proximal tip, a distal end region terminating in a distal tip 64, and an outer surface 34 defining a second lumen 28 (See Figure 4A) extending longitudinally therethrough between distal and proximal openings.

Figure 4A shows that the catheter 26 has an outer surface 34 defined by a rounded wall portion 36 and a flat side surface 38 and the catheter 30 has an outer surface 40 defined by a rounded wall portion 42 and a flat side surface 44. The flat surfaces 38, 44 are spaced from each other and form a part of separate walls defining the lumen 28 and the lumen 32 respectively. In

addition to two separate walls being located between the lumens 28, 32, the splittable membrane 46 joins the flat surfaces 38, 44 of the separate walls by extending across a gap formed between the separate walls.

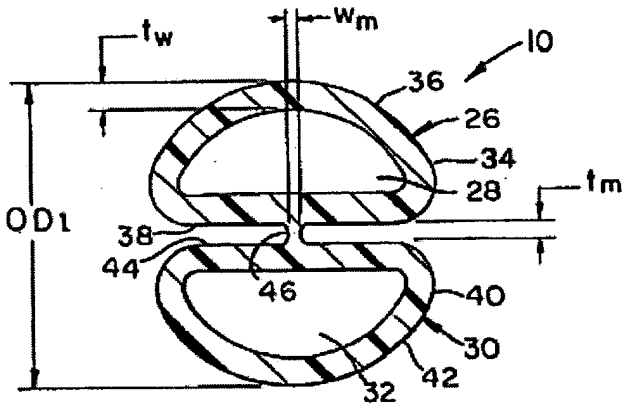

FIG. 4A

The multiple wall and thin membrane arrangement is included in all illustrated embodiments. See Figures 4B, 4C, 4D, 4E, and 4F and G.

Although enabling insertion of the catheter 10 as a single catheter, the membrane 46 is provided to allow the first and second catheters 26, 30 to be at least partially longitudinally split from each other. Column 6, lines 30-63. This is accomplished by making the membrane 46 relatively thin and of a material that will tear upon application of forces to the catheters 26, 30. This arrangement is intended to provide the advantages of separate catheter designs, which have distal ends and fluid outlets that are independently movable to permit intake and/or return around the entire circumference of both distal ends. See Column 2, lines 5-18 and 36-41. If only a single wall extended between the lumens 28, 32 the lumens would be inseparable, eliminating the benefit of the membrane 46.

Claims 1 and 4-12

In contrast, Claim 1, as amended, recites a multilumen catheter for directing the flow of blood through a patient through a single cannulation site, said catheter comprising:

> a catheter body having a proximal end configured to enable the catheter to be applied through a single cannulation site, a first distal end, and a second distal end, said first distal end extending distally further from the proximal end than the second distal end and said second distal end being closer to the proximal end than to the first distal end;

a first lumen at least partially defined by a wall for passing blood through the body extending between said first distal end and said proximal end adapted to fluidly communicate with the patient;

a second lumen at least partially defined by the wall for passing blood through the body extending between said second distal end and said proximal end adapted to fluidly communicate with the body independently of the first lumen; and

at least one aperture on said body communicating with said first lumen, wherein the distance from the first distal end to the aperture is a first length, the distance from the second distal end to the aperture is a second length, and the distance from the first distal end to the second distal end is a third length, wherein the first length is greater than the third length and the first length is at least three times greater than the second length;

said catheter body having a continuous outer surface surrounding said first and said second lumens along at least a portion of said body distal of said aperture;

wherein at a location where the distance between the first and second lumens is smallest, only a single wall extends between the first and second lumens at least at the second distal end.

Applicants respectfully submit that Ash does not teach or suggest all of the foregoing limitations of Claim 1 as amended. Accordingly, amended Claim 1 is patentably distinguished over Ash. Applicants respectfully request the Examiner to withdraw the rejection of Claim 1 based on Ash.

Claims 4-12 depend from Claim 1 and further define the invention defined in Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicants respectfully submit that Claims 4-12 are patentably distinguished over Ash. Claims 4-12 also are patentably distinguished over Ash in view of the additional limitations defined in the claims. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of Claims 4-12 based on Ash.

Claims 27-30

Similarly Claim 27 recites an extracardiac pumping system for supplementing blood circulation in a patient without any component thereof being connected to the patient's heart, the extracardiac system comprising:

a pump configured to pump blood through the patient at subcardiac flow rates, said pump having an average flow rate that, during normal operation thereof, is substantially below that of the patient's heart when healthy;

an inflow conduit fluidly coupled to the pump to direct blood to the pump from a first blood vessel;

an outflow conduit fluidly coupled to the pump to direct blood from the pump to a second blood vessel; and

a multilumen catheter for directing the flow of blood through a patient through a single cannulation site, said catheter comprising

a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally further from the proximal end than the second distal end;

a first lumen extending between said first distal end and said proximal end, said first lumen in fluid communication with one of said conduits; and

a second lumen extending between said second distal end and said proximal end, said second lumen in fluid communication with one of said conduits, wherein the pump is oriented to deliver fluid from the pump to the second lumen;

wherein at a location where the distance between the first and second lumens is smallest, only a single wall extends between the first and second lumens at least at the second distal end.

Applicants respectfully submit that Ash does not teach or suggest all of the foregoing limitations of Claim 27 as amended. Accordingly, amended Claim 27 is patentably distinguished over Ash. Applicants respectfully request the Examiner to withdraw the rejection of Claim 27 based on Ash.

Claims 28-30 depend from Claim 27 and further define the invention defined in Claim 27. For at least the reasons set forth above with respect to Claim 27, Applicants respectfully submit that Claims 28-30 are patentably distinguished over Ash. Claims 28-30 also are patentably distinguished over Ash in view of the additional limitations defined in the claims. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of Claims 28-30 based on Ash.

Rejections Based on Schweikert

Claims 1, 4, 9-12, and 27-30 are rejected in the Office Action under 35 U.S.C. § 102(e) as anticipated by Schweikert (U.S. Patent No. 6,719,749 to Schweikert et al.). Additionally, Claims 5 and 6 are rejected under 35 U.S.C. § 103(a) as obvious in view of Schweikert.

Schweikert

Schweikert is directed to a multilumen catheter assembly 10 and related methods. The assembly 10 includes a first distal end tube 26 which has an outer surface 34 defining a first passageway extending longitudinally through the distal end tube 26. A second distal end tube 30 has an outer surface 40 defining a second longitudinally extending passageway. The first and second passageways are in fluid communication with a first lumen and second lumen respectively of a unitary catheter 20. The separate distal end tubes 26, 30 are shown in Figure 1, below.

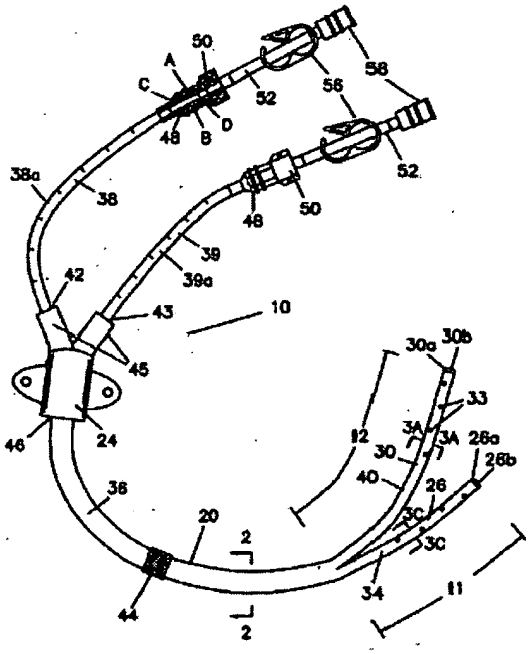

FIG. 1

The Schweikert construction provides discontinuous surfaces around the first and second passageways 28, 32. Additionally, each of the outer surfaces 34, 40 defines a part of separate walls surrounding the passageways 28, 32 at the distal of the tube 26. Schweikert teaches that between their respective distal ends and the unitary catheter 20, the "distal end tubes 26, 30 are capable of independent movement and are not attached to each other." Column 7, lines 1-3. The

Schweikert structure is similar to the Ash Structure in that multiple walls (as well as a relatively large gap) extend between the first and second lumens at the distal end of the tube 26.

Claims 1, 4, and 9-12

In contrast, Claim 1, as amended, recites a multilumen catheter for directing the flow of blood through a patient through a single cannulation site, said catheter comprising:

> a catheter body having a proximal end configured to enable the catheter to be applied through a single cannulation site, a first distal end, and a second distal end, said first distal end extending distally further from the proximal end than the second distal end and said second distal end being closer to the proximal end than to the first distal end;
>
> a first lumen at least partially defined by a wall for passing blood through the body extending between said first distal end and said proximal end adapted to fluidly communicate with the patient;
>
> a second lumen at least partially defined by the wall for passing blood through the body extending between said second distal end and said proximal end adapted to fluidly communicate with the body independently of the first lumen; and
>
> at least one aperture on said body communicating with said first lumen, wherein the distance from the first distal end to the aperture is a first length, the distance from the second distal end to the aperture is a second length, and the distance from the first distal end to the second distal end is a third length, wherein the first length is greater than the third length and the first length is at least three times greater than the second length;
>
> said catheter body having a continuous outer surface surrounding said first and said second lumens along at least a portion of said body distal of said aperture;
>
> wherein at a location where the distance between the first and second lumens is smallest, only a single wall extends between the first and second lumens at least at the second distal end.

Applicants respectfully submit that Schweikert does not teach or suggest all of the limitations of Claim 1 as amended. Accordingly, amended Claim 1 is patentably distinguished over Schweikert. Applicants respectfully request the Examiner to withdraw the rejection of Claim 1 based on Schweikert.

Claims 4 and 9-12 depend from Claim 1 and further define the invention defined in Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicants respectfully submit

that Claims 4 and 9-12 are patentably distinguished over Schweikert. Claims 4 and 9-12 also are patentably distinguished over Schweikert in view of the additional limitations defined in the claims. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of Claims 4 and 9-12 based on Schweikert.

Claims 5 and 6

As discussed above, Claims 5 and 6 have been rejected as obvious in view of Schweikert. However, Claims 5 and 6 depend from Claim 1 and further define the invention defined in Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicants respectfully submit that Claims 5 and 6 are patentably distinguished over Schweikert. Claims 5 and 6 also are patentably distinguished over Schweikert in view of the additional limitations defined in each of the claims. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of Claims 5 and 6 based on Schweikert.

Claims 27-30

Amended Claim 27 also is patentably distinguished over Schweikert. In particular, Claim 27 recites an extracardiac pumping system for supplementing blood circulation in a patient without any component thereof being connected to the patient's heart, the extracardiac system comprising:

> a pump configured to pump blood through the patient at subcardiac flow rates, said pump having an average flow rate that, during normal operation thereof, is substantially below that of the patient's heart when healthy;
>
> an inflow conduit fluidly coupled to the pump to direct blood to the pump from a first blood vessel;
>
> an outflow conduit fluidly coupled to the pump to direct blood from the pump to a second blood vessel; and
>
> a multilumen catheter for directing the flow of blood through a patient through a single cannulation site, said catheter comprising
>
> > a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally further from the proximal end than the second distal end;
> >
> > a first lumen extending between said first distal end and said proximal end, said first lumen in fluid communication with one of said conduits; and

a second lumen extending between said second distal end and said proximal end, said second lumen in fluid communication with one of said conduits, wherein the pump is oriented to deliver fluid from the pump to the second lumen;

wherein at a location where the distance between the first and second lumens is smallest, only a single wall extends between the first and second lumens at least at the second distal end.

Applicants respectfully submit that Schweikert does not teach or suggest all of the foregoing limitations of Claim 27 as amended. Accordingly, amended Claim 27 is patentably distinguished over Schweikert. Applicants respectfully request the Examiner to withdraw the rejection of Claim 27 based on Schweikert. Applicants do not necessarily agree that Claim 27 as previously pending was not patentable over Schweikert. However, the foregoing amendment has been made to expedite allowance of this application.

Claims 28-30 depend from Claim 27 and further define the invention defined in Claim 27. For at least the reasons set forth above with respect to Claim 27, Applicants respectfully submit that Claims 28-30 are patentably distinguished over Schweikert. Claims 28-30 also are patentably distinguished over Schweikert in view of the additional limitations defined in the claims. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of Claims 28-30 based on Schweikert.

Rejection Based on Runge

Claims 27-30 are rejected in the Office Action under 35 U.S.C. § 103(a) as obvious in view of Runge (U.S. Patent No. 5,785,686). Applicants note that this rejection briefly discusses the definiteness of the flow rate limitation. However, a prior rejection of these claims as indefinite has not been maintained and is believed to have been withdrawn. In connection with Runge, the Examiner proposes further amendment to Claim 27 to clarify that the pump is oriented to deliver fluid from the pump to the second lumen to further clarify that the Runge reference is not within the scope of the claims in that Runge is arranged so that blood is drained from heart chambers of a patient into a shorter lumen via orifices. Applicants have made this amendment herein. Accordingly, Claims 27, as amended, is patentably distinguished over Runge.

Claims 28-30 depend from Claim 27 and further define the invention defined in Claim 27. For at least the reasons set forth above with respect to Claim 27, Applicants respectfully

submit that Claims 28-30 are patentably distinguished over Runge. Claims 28-30 also are patentably distinguished over Runge in view of the additional limitations defined in the claims. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of Claims 27-30 based on Runge.

SUMMARY

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and Applicants respectfully request that a Notice of Allowance be issued at the earliest opportunity.

Respectfully submitted,

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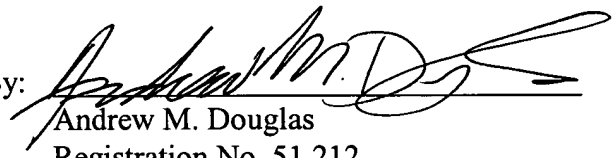
Dated: December 21, 2004

By: 

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